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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,313	11/28/2000	Elmar Reinhold Burchardt	LeA 32 701	8752
28524 7590 05/19/2008 SIEMENS CORPORATION INTELLECTUAL PROPERTY DEPARTMENT 170 WOOD AVENUE SOUTH ISELIN, NJ 08830				
EXAMINER HADDAD, MAHER M				
ART UNIT		PAPER NUMBER		
1644				
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05/19/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

09/701,313

**Applicant(s)**

BURCHARDT ET AL.

**Examiner**

Maher M. Haddad

**Art Unit**

1644

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2 and 6-10 is/are pending in the application.
- 4a) Of the above claim(s) 8-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2 and 6-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/88)
- Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

#### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/27/08 has been entered.

2. Claims 1-2 and 6-10 are pending.

3. Amended claims 8-10 are directed to an invention that is independent and distinct from the invention originally claimed for the following reasons: Claims 8-10 are now recites a sandwich immunoassay which is method claims. Applicant points to both Examples 8 and 9 of the specification for support for the term sandwich immunoassay as a product. Applicant argues that it would be readily apparent to one of ordinary skill in the art that the inventors were in possession of the physical embodiment of "sandwich immunoassay," particularly in view of the fact that Example 9 makes reference to the fact that such an assay was "set up" --a phrase which more commonly references a noun than a verb. However, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). Further, obviousness is not the standard for the addition of new limitations to the disclosure as filed. It is noted that entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977). It remains the Examiner's position that the terms are used as a verb. The restriction requirements mailed 03/08/07, placed such claims under Group II, however, Applicant elected Group I. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 8-10 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.

The Examiner would like to remind Applicant that when applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined. See MPEP § 804.01. It is noted that Claims 8-10 are messing method step.

4. Claims 8-10 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

5. Claims 1-2 and 6-7 are under examination in the instant application as they read on a monoclonal antibody directed against an epitope within the 30 most N-terminal amino acids of

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human PIINP, or an oligopeptide with the sequence derived from the N-terminal peptide is of Co12 domain of PIINP, and the 30 most N-terminal amino acids of human PIINP as the specie.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112.

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

7. Claims 6-7 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- A) Claims 6-7 are indefinite in the recitation of "35J22" and "35J23" because its characteristics are not known. The use of "35J22" and "35J23" monoclonal antibodies as the sole means of identifying the claimed antibody and hybridoma renders the claim indefinite because "35J22" and "35J23" is merely a laboratory designation which does not clearly define the claimed product, since different laboratories may use the same laboratory designations to define completely distinct hybridomas or cell lines. It is suggested that the deposit accession No. be cited in the claims.

Applicant's arguments, filed 3/27/08, have been fully considered, but have not been found convincing.

Applicant submits that a "Statement under 37 C.F.R. § 1.809(b)(1)" signed by the Applicant assuring the Office that acceptable deposits of the 35J22 and 35J23 cell lines, conforming to the requirements of 37 C.F.R. § 1.801-809, will be made on or before the date of payment of the issue fee.

The rejection is maintained until the deposit accession No. is cited in the claim.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

9. Claims 6-7 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the hybridoma that produce 35J22 and 35J23 mAb antibodies are required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, a deposit of the hybridoma, which produces this antibody, may satisfy first paragraph. See 37 CFR 1.801-1.809.

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Applicant's arguments, filed 3/27/08, have been fully considered, but have not been found convincing.

Applicant submits that a "Statement under 37 C.F.R. § 1.809(b)(1)" signed by the Applicant assuring the Office that acceptable deposits of the 35J22 and 35J23 cell lines, conforming to the requirements of 37 C.F.R. § 1.801-809, will be made on or before the date of payment of the issue fee.

The rejection is maintained until the deposit accession statement is provided.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-2 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Brocks et al , 1993, (IDS ref.) in view of U.S. Pat. No. 5,512,283, as is evidenced by GenBank accession No. P02461 for the same reasons set forth in the previous Office Actions mailed 6/4/07 and 10/29/07.

Applicant's arguments, filed 3/27/08, have been fully considered, but have not been found convincing.

Applicants traverse this rejection on the grounds that Brocks does not teach or suggest a monoclonal antibody directed against an epitope within the 30 most N-terminal amino acids of the Col I domain of human PIIINP. Table 1 of Brocks shows epitope scanning data for the polyclonal antibody-containing antiserum against bovine N-terminal propeptide of procollagen type III. There is nothing in this reactivity profile that would have directed one skilled in the art to prepare a monoclonal antibody against an epitope in the range of amino acids 25 to 54 (the 30 most N-terminal amino acids of the Coll domain). Notably, the most significant reactivity was for the pin carrying the peptide representing amino acids 142-149. There is no significant reactivity in the range of amino acids 25 to 54 that would have directed one of ordinary skill in the art to select that region for producing a monoclonal antibody. In fact, the reactivity in the range of amino acids 25 to 54 does not appear to be any greater than the reactivity against the entire sequence up to the sharp peak near residue 140. Therefore, there is nothing to differentiate

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this region or to recommend forming a monoclonal antibody against it. The contention that Brocks would have motivated one skilled in the art to make a monoclonal antibody directed against an epitope within the range of amino acids 25 to 54 (the 30 most N-terminal amino acids of the Col 1 domain) is impermissibly based on hindsight.

However, it remains the Examiner's position that in the antibody art, an antibody to any epitope within the claimed sequence (24-54 of claimed SEQ ID NO: 2) would bind to the claimed 30 most N-terminal amino acids of the Col 1 domain of human PIIINP. That is an antibody to a peptide of 8 amino acids that shares 100% sequence homology with the claimed sequence would bind to the claimed sequence. Accordingly, the resultant mAb to the octopeptides taught by the combined reference teachings would result in binding to an epitope within the 30 most N-terminal amino acids of the Col 1 domain of human PIIINP. The Examiner acknowledges the weak binding of the antisera antibody to the cited octopeptides that shares 100% homology with the claimed 30 most N-terminal amino acids of the Col 1 domain of human PIIINP in Brocks. However, such teachings provide motivation to make monoclonal antibodies to said octopeptides as taught by the '283 patent.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on (571) 272-0878. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 15, 2008

/Maher M. Haddad/  
Primary Examiner,  
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